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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/611,257 07/06/00 SNUTCH

T 381092000721

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HM22/1003

EXAMINER

BASI,N

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

10/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/611,257

Applicant(s)
Snutch et al

Examiner
Nirmal S. Basi

Art Unit
1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6 and 14, drawn to a DNA molecule which comprises an expression cassette comprising a nucleotide encoding a T-type calcium channel α_1 subunit, , cells containing said expression cassette, classified in class 536 , subclass 23.1, for example .
- II. Claims 7, drawn to identify a compound as modulator for T-type mammalian calcium channel using the cell of claim 6, classified in class 435 , subclass 4.

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III. Claim 8 drawn to a T-type calcium channel modulator identified by the method of claim 7, class and subclass cannot be defined because the modulator is not disclosed.

5 IV. Claims 9 and 10, drawn to a method to treat conditions characterized by undesirable levels of T-type calcium channel activity said method comprising the administration of the modulator of claim 8, class and subclass cannot be defined because the modulator is not disclosed.

10 V. Claim 11, drawn to a DNA molecule which comprises an expression system for a nucleotide sequence which is complementary to the nucleotide sequence encoding a T-type calcium channel α_1 subunit, classified in class 536, subclass 24.5.

15 VI. Claims 12 and 13, drawn to a method to treat conditions characterized by undesirable levels of T-type calcium channel activity said method comprising the administration of the DNA molecule of claim 11, classified in class 514, subclass 44.

VII. Claim 15, drawn to a method to map the distribution T-type calcium channels in a tissue which method comprises contacting said tissue with the oligonucleotide of claim 4, classified in class 435, subclass 6.

20 VIII. Claims 16, drawn to an antibodies specifically immunoreactive with the extracellular portions of a T-type calcium channel, class 530, subclass 387.1.

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IX. Claim 17, drawn to a method to map the distribution T-type calcium channels in a tissue which method comprises contacting said tissue with the antibodies of claim 4, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

5

The compounds of I, III, V and VIII are distinct from each other because they structurally and functionally different and are capable of separate use and manufacture.

10 The compounds of Inventions I and the methods of Invention II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids contained in the cells of Invention I can be used produce the encoded protein.

15 The compounds of Invention I are distinct from the methods of Invention IV, VI and IX wherein the compounds of Invention I can neither be used in nor made by the methods of Invention IV, VI and IX.

The methods of Inventions II, IV, VI and IX are distinct from each other because they are independent, using separate method steps, active agents and having different effects.

20 The compounds of Inventions III and the methods of Invention IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following

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can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compounds of Inventions III can be used produce antibodies.

5 The compounds of Invention III are distinct from the methods of Invention II, VI, VII and IX wherein the compounds of Invention III can neither be used in nor made by the methods of Invention II, VI, VII and IX.

10 The compounds of Inventions V and the methods of Invention VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case compounds of Inventions can be used a hybridization probes.

15 The compounds of Invention V are distinct from the methods of Invention II, IV VII and IX wherein the compounds of Invention III can neither be used in nor made by the methods of Invention II, IV VII and IX.

20 The compounds of Inventions VIII and the methods of Invention IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case compounds of can be used to purify protein.

The compounds of Invention VIII are distinct from the methods of Invention II, IV, VI and VII wherein the compounds of Invention III can neither be used in nor made by the methods of Invention II, IV, VI and VII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art, restriction for examination purposes as indicated is proper. A search of the art for Inventions I-IX would not be co-extensive with each other. Because the searches required for these inventions are not co-extensive an examination of the materially different, patentably distinct inventions in a single application would constitute a serious burden on the examiner.

The claims of group I-IX are drawn to a multitude of nucleic acids encoding distinct T-type calcium channel alpha subunits disclosed as α_{1G} , α_{1H} , α_{1I} , immunoglobulins thereto and methods which use these calcium channel alpha subunits. The claims apply to numerous calcium channel alpha subunits. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different nucleic acids//antibodies/and methods of use are independent and distinct because no common structural or functional properties are shared. There is no description of definitive structural or functional features of the claimed Markush group. The Markush group contains no conserved regions which are critical to the structure and function of the genus claimed. The common function of the

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claimed genus of polynucleotides, which is based upon a common property or critical technical feature of the genus claimed is not disclosed. Accordingly, these claims are subject to restriction under U.S.C. § 121. Upon election of Groups I-IX, Applicants is additionally required to elect a single nucleic acid, polypeptide, or antibody pertaining to T-type calcium channel alpha subunits disclosed as α_{IG} α_{IH} α_{II} . This requirement is not to be constructed as a requirement for election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

An election to prosecute one of the groups listed I-IX must be made. Affirmation of this election must be made by applicant in responding to this Office action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nirmal Basi whose telephone number is (703) 308-9435. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 308-0294.

Serial Number: 09/611257

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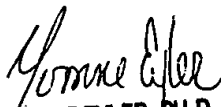
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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

5 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Nirmal S. Basi
Art Unit 1646
September 30, 2001

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YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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